Bilateral Meeting with European Commission Director General for Health and Food Safety Anne Bucher

May 2, 2019 *4:00-5:00 PM:*	**Bilateral Meeting with European Commission Director General for Health and Food Safety (DG SANTE) Anne Bucher**
Location:	TBD – Near the DG Environment Offices
Attendees:	*EC* – **Anne Bucher, Director General** and staff *EPA* – **You,** Ryan Jackson, Michael Molina, Mark Kasman, James Hewitt, Chris Beach (TBC)
Annotated Agenda:	There is no formal agenda for this meeting (TBC). This meeting serves as an opportunity to meet a key counterpart on pesticides issues and to have an open discussion on current challenges and raise bilateral awareness, working to build communication channels and better understanding of our approaches.
Notes:	TBD
Press:	Closed meeting

Bio:

European Commission Director-General for Health and Food Safety (DG SANTE)– Anne Bucher

Bucher assumed her responsibilities as head of the Director-General for Health and Food Safety (DG SANTE) for the European Commission on October 1, 2018. Of French nationality, Bucher has worked for the European Commission for 35 years. During most of her career, she has held management positions. Since 2008, she has been a senior manager in the Commission's Directorates-General for economic affairs and for communications networks, content and technology. She was also the economic advisor in the European Union (EU) Delegation in Lusaka, Zambia.

Bucher has Masters degrees in statistics from ENSAE (Ecole Nationale de Statistique et Administration Economique) and economics from University Paris I-Sorbonne, as well as a PhD in applied macroeconomics from E.H.E.S.S. (Ecole des Hautes Etudes en Sciences Sociales). She speaks French, English and German.

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Talking Points

- It is a pleasure to meet you, Director General Bucher, and I look forward to the opportunity to share our thoughts and perspectives on pesticides today.

- **Ex. 5 Deliberative Process (DP)**

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Background:
You are in town to meet with DG Calleja and DG Environment, however the U.S. Mission in Brussels asked that we add this meeting with DG SANTE to your schedule given the importance of the pesticide issues. You will touch on pesticides/MRLs issues during your meeting with DG Calleja on May 3, and the discussion with DG SANTE the day before will provide you with more in-depth information on these issues.

As highlighted in the briefing on this issue from OCSPP prior to your departure, the USG and U.S. industry have significant issues with EU pesticide policy. Through the U.S. Mission in Brussels, the USG is working at a technical level to engage with the EU on their policies. During the week of April 1, 2019, technical experts from OCSPP/EPA (OPP and OSCP), USDA, and USTR meet with the EU in Brussels to exchange information and compare current practices, procedures, and overall pesticide regulatory approaches. We hope in your discussions with DG Bucher that you can underscore our interest in promoting better cooperation in areas where we have divergent views and help demonstrate U.S. willingness to strengthen transatlantic relations, consistent with our commitment to a science-risk-based approach to pesticides management.

U.S.-EU Pesticide Approaches

EPA uses a risk-based approach to pesticide regulation, considering both the hazard and potential exposure, with a rigorous risk assessment and risk management process. In contrast, the European Union's Regulation 1107/2009, which governs the registration of crop protection products, establishes several hazard-based "cut-off" criteria that exclude certain categories of products from consideration for normal authorized use in the EU. Those "cut off" criteria include any crop protection product that is an endocrine disruptor, neurotoxic, or immunotoxic. For such products, the EU would not perform a risk assessment. Rather, the EU would discontinue authorization at the time of re-approval or, in the case of new products, declare them to be ineligible for authorization based solely on the determination that they are an endocrine disruptor, neurotoxic, or immunotoxic, without taking into account important risk factors, such as level of exposure.

A separate EU regulation, EC Regulation No. 396/2005, establishes MRLs and import tolerances. The decision-making process under this regulation is nominally risk-based rather than hazard-based. However, it is possible that for substances *not* approved under Regulation 1107/2009 due to the cut-off criteria, the EU may forgo the risk assessment process and automatically reset the MRLs and import tolerances to the default level of 0.01 mg/kg. From our perspective, these hazard-based "cut-off" criteria use arbitrary thresholds for adverse effects, and do not consider important factors like dosage or exposure, which we see as critical in determining whether an adverse effect is likely to occur.

Lastly, a hazard-based approach is inconsistent with the approach to setting standards (MRLs) for pesticides outlined in the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), to which both the U.S. and the EU are Parties. The SPS Agreement sets out the basic rules for food safety and animal and plant health standards, allowing countries to set their own standards but, at the same time, requiring regulations to be based on science. In other words, the SPS agreement allows the sovereign right of any government to provide the level of protection it deems appropriate, but those levels are to

be based on appropriate assessments of risk. The agreement also restricts the use of unjustified measures for the purpose of trade protection.